

VZCZCXRO8172
PP RUEHAG RUEHAP RUEHDE RUEHDF RUEHGI RUEHHM RUEHLZ RUEHMA RUEHMR
RUEHPA RUEHPB RUEHRN
DE RUEHRH #2139/01 2971454
ZNR UUUUU ZZH
P 241454Z OCT 07
FM AMEMBASSY RIYADH
TO RUEHC/SECSTATE WASHDC PRIORITY 6792
INFO RUCNWTO/WORLD TRADE ORGANIZATION COLLECTIVE PRIORITY
RUCPDO/DEPT OF COMMERCE WASHDC PRIORITY

UNCLAS SECTION 01 OF 02 RIYADH 002139

SIPDIS

SENSITIVE
SIPDIS

USTR FOR JASON BUNTIN
USDOC FOR TYLER HOFFMAN

E.O. 12958: N/A
TAGS: [ETRD](#) [EINV](#) [KIPR](#) [SA](#)
SUBJECT: SAUDI ARABIA PHRMA ISSUES: REQUEST FOR GUIDANCE

REF: A. RIYADH 1346
[1](#)B. RIYADH 1347

[1](#)1. This is an action request for EEB/TPP/BTA, USDOC and USTR. Please see paragraph 9.

[1](#)2. (SBU) Summary. Multinational pharmaceutical companies are vigorously lobbying Post, the Department, USDOC and USTR for high-level USG involvement in two ongoing issues impacting their interests in Saudi Arabia. Over the last year, the government of Saudi Arabia has cut prices for pharmaceutical products sold in the Kingdom, and removed patent protection for an unknown number of pharmaceutical products during the country's transition to a new TRIPS-compliant patent law in 2004 (reftel A, B). Affected pharmaceutical companies argue that the SAG's actions violate its WTO obligations. Post requests (a) USTR's guidance on whether the SAG is in violation of its WTO obligations as alleged by industry, and (b) the Department's guidance as to appropriate USG intervention, if any, in these issues. Industry is likely to raise these issues during the upcoming visit of Assistant US Trade Representative Donnelly, making clarification of the USG position especially timely. End Summary.

MOH Announces Price Cuts
To Take Effect During Ramadan

[1](#)3. (SBU) In October 2006, the Saudi Arabian Ministry of Health (MOH) stated its intention to reduce pharmaceutical prices in the Kingdom by 1 percent for each year a product has been on the market. On September 11, 2007, the MOH released an additional statement saying that it would announce price cuts on more than 6,000 medicines during the September-October period of Ramadan. (Note: The price cuts have not yet gone into effect, but industry contacts expect them to be announced on October 30. End note.) According to industry representatives in Riyadh, the SAG proposes to exempt only products that cost less than SR20 (US\$5.33) or those which were registered in the last five years (up from an initial proposal of two years) from the 1 percent per year price reduction policy.

Industry Claims MOH Refuses Consultations

[1](#)4. (SBU) In a meeting with Emboffs on September 11, industry representatives expressed deep frustration with the MOH's refusal to consult with them regarding this proposed pricing mechanism. They state the SAG has granted them only

one meeting on this issue. During this late June meeting with Ali Zawawi, General Director of Medical and Pharmaceutical Licenses at the MOH, the industry representatives stated their concerns were not heard and their questions were not answered. They further assert that the SAG would violate its WTO obligations if it implemented this pricing mechanism without formally issuing a written explanation of the mechanism and allowing 60 days for public comment. The representatives requested that the USG intervene to stop the SAG from implementing this pricing mechanism and to convince it to engage with industry.

15. (SBU) The Ambassadors of the European Union, Switzerland and Belgium to Saudi Arabia met with the Minister of Health regarding the proposed pricing mechanism on September 26. According to industry contacts, the Minister acknowledged that it is in the long-term interests of Saudi Arabia to consult with European pharmaceutical companies regarding pricing. He stated that the MOH would not implement a new pricing mechanism without consulting with industry and that the MOH would meet with industry representatives in the coming month. Those representatives report that no such meetings have occurred.

Loss of Patent Protection

16. (SBU) An unknown number of pharmaceutical products lost patent protection when Saudi Arabia transitioned to a new TRIPS-compliant patent law in 2004. Products that had applications for patents pending under the old law (and enjoyed patent protection while their applications were pending) were reviewed as new cases under the new law. According to Dr. Khalid Alakeel, Director General of

RIYADH 00002139 002 OF 002

Industrial Property at the King Abdulaziz City for Science & Technology (KACST), these products were then denied patents because the SAG determined that they were not "novel" because they had been publicly patented in other jurisdictions more than a year before their cases were considered in Saudi Arabia. USTR proposed that the SAG grant temporary exclusive marketing rights to pharmaceutical products in this category.

The SAG asked for a list of these products, but industry was reluctant to provide a definitive list for fear of inadvertently omitting a product. Fawaz al-Alamy, Advisor to the Minister of Commerce and Information, suggested to Paul Burkhead (former Director for European and Middle Eastern Trade Affairs at USTR) on June 4, 2007, that industry at least provide a list of examples to give the SAG an idea of the extent of the problem. Industry has not yet provided any list to the SAG, though Post understands that such a list is now in the final stages of compilation.

17. (SBU) The September 11 MOH statement also stated the price of Lipitor had been reduced from SR140 (US\$37.33) to SR76 (US\$20.26). MOH has licensed a local manufacturer to produce a generic version of Lipitor, effectively cutting the drug's price. To Post's knowledge, Lipitor is the first pharmaceutical to lose patent protection under the process outlined above, for which the MOH has subsequently licensed manufacture of a generic equivalent. Pfizer, Lipitor's manufacturer, is appealing the decision to deny Lipitor a patent, and argues that MOH's issuance of a license to manufacture generic Lipitor violates Saudi Arabia's WTO obligations. Pfizer states that under Saudi Arabia's Protocol of Access to the WTO, the Saudi Arabian representative stated that if a pharmaceutical patent application was pending with KACST, the MOH would not register a generic, unless there was no possibility that the patent would be granted.

18. (SBU) During an October 24 meeting with Emboff, Alakeel acknowledged that Pfizer is in the process of appealing

Lipitor's rejected application. He further agreed in principle that a license to produce a generic version of a pharmaceutical should not be issued while the patent rejection of that precise pharmaceutical is being appealed. However, he explained that pharmaceuticals can be patented in five different ways (e.g. each of the drug's different physical forms and the process of making the drug) and Pfizer had only applied to patent Lipitor in three of those ways, so it is possible that Pfizer did not apply to patent the form of Lipitor for which the MOH issued a generic license. Alakeel said he was not aware of whether this was in fact the case. He also reiterated that the SAG was willing to explore a solution for the pharmaceutical products that lost patent protection, but stated that such a process would not progress until industry provides a list of affected products to the SAG.

Request for Guidance

19. Action Request: AUSTR Shaun Donnelly has proposed to visit Riyadh in early 2008. Industry will likely take the visit as an opportunity to further press their agenda; these issues may also come up during AUSTR Donnelly's official meetings. Post therefore recommends clarifying a comprehensive USG response prior to his visit. Post requests that USTR clarify its views on possible WTO violations alleged by industry, as described above. Post also requests instructions from EEB/TPP/BTA, Commerce and USTR and regarding how and to what extent we should advocate on behalf of the US pharmaceutical industry on these issues.
FRAKER